

REMARKS

In the Office Action mailed from the United States Patent and Trademark Office on October 16, 2008, claims 7-9 were rejected under 35 U.S.C. 112; claims 1-2 and 7-9 were rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,250,035 to Smith et al. (“Smith”) in view of U.S. Patent Publication No. 2002/0123723 to Sorenson et al. (“Sorenson”); and claims 3-6 were rejected under 35 U.S.C. 103(a) as being unpatentable over Smith et al. and Sorenson in further view of U.S. Patent Publication No. 2002/055715 to Young et al. (“Young”).

Applicant respectfully submits that the cited references, alone or in combination, do not teach or suggest all the limitations recited in the claim set provided herein. In particular independent claims 1, 5 and 7 contain limitations drawn to a hollow needle having thirteen fenestrations longitudinally isolated to within three centimeters of the distal end of said hollow needle. Specification, page 7, lines 12-22.

The pending action relies on Sorenson to teach modifying Smith’s needle to include multiple apertures “because doing so provides a wider distribution of fluid than with a single opening (Sorenson et al, Paragraph [0033]).” Office Action, page 4. In accord with the Examiner’s observations, Sorenson teaches an apparatus for specific subcutaneous diffusion and dispersion of medication along the tubular element’s length. Sorenson, abstract. Accordingly, Sorenson discloses a method of administering medicine along the entire length of the needle inserted into a patient.

Independent claims 1, 5 and 7, contain a limitation requiring that the fenestrations are isolated on a distal end of the fenestrated needle. This is very different than the plurality of perforations disclosed in Sorenson that release anesthetics along its entire length so that it uniformly disperses medication to a treatment zone. Sorenson, paragraph 33. Sorenson specifically differentiates itself from the “point-source” fluid introduction of other devices. In contrast to the broad, uniform release strategy of Sorenson, the present invention focuses on precisely placing its injections in order to avoid intravascular injection and/or inadvertent

penetration of a nerve. Specification, page 3, lines 20-22. Because the space in the facial plain is very small and located proximate a nerve exact dispersion of medicine is required. Thus, it would be dangerous to apply the teachings of Sorenson to the present invention, as application of Sorenson's invention would send anesthetic outside the boundaries of the well defined facial compartments in which Applicant directs the anesthetic.

The importance of localizing the fenestrations near the distal end of the needle is elucidated in a non-limiting example found on page 8 of the specification, which indicates that "fenestrations are preferably located within one or two millimeters, and most preferably within 0.17 inches of each other for this purpose," wherein said purpose is to "deliver drug approximate to the lower extremity nerves which comprise only a few millimeters in width, for example a discrete compartment of only a few millimeters is located between the semitendinosus muscle 32 and bicep femoris muscle 34. This facial compartment 30 houses the sciatic nerve 36, one of two major lower extremity nerves, fenestrations 20 are spaced at relatively small intervals along the needle 12 in order to maximize an even distribution of local anesthetic to any particular facial compartment 30, including particularly male compartments such as the housing of the sciatic nerve 36." Specification, pg. 8, lns. 7-17. Use of Sorenson's needle and its release of drugs along the entire length of the needle produces a dangerous situation if utilized to administer drugs to block peripheral nerves as claimed by the present application. Because the combination of art does not teach every limitation of the claimed invention, Applicant respectfully requests that the Examiner withdraw his Section 103 rejection.

CONCLUSION

If any impediments to the allowance of this application for patent remain after the above amendments and remarks are entered, the Examiner is invited to initiate a telephone conference with the undersigned attorney of record.

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Respectfully submitted,


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